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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,948	08/26/2003	Harvey Jay	J07-004	4553

7590 04/18/2005

R. Neil Sudol
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,948	JAY, HARVEY	
	Examiner	Art Unit	
	Henry M Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-19,22-29,31-40,58 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-19,22-29,31-40,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive. The allowability of claims 11-15, 19, 24, 30-36 and 60, after reevaluation of the disclosure is withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 12-19, 22-29, 31-40 and 58-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a *specific, substantial and credible* asserted utility or a well established utility.

An invention must produce a concrete, tangible and useful result. The method claims cite no specific benefit. The benefits of "reducing, preventing or inhibiting" are interpreted as too sweeping in context to yield any specific result. Disclosure of only a general utility rather than a particular utility is insufficient to the meet statutory requirement. When it is speculative as to whether the invention achieves the asserted utility, then the invention lacks a specific utility. See Rey-Bellet v. Englehardt, 493 F.2d 1380, 1383-84, 181 USPQ 453, 454-56 (CCPA 1974). A substantial utility requires a "real world" use. Utilities that require carrying out further research to identify or reasonably confirm such use, do not have substantial utility. The disclosure provides no details to substantiate the utility, thus suggesting additional research is required. The credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record. No substantiated test or trial results are cited. The number of variables disclosed regarding the radiation and the treatment site (skin type) are

many with wide ranges, making it speculative as to whether the invention achieves the asserted utility, thus credibility is lacking. Another consideration is whether the invention produces a concrete result. The sweeping range of variables raises the question of an ability to produce the same result on a consistent basis. No evidence is provided that the results can be assured.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 12-19, 22-29, 31-40 and 58-59 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a *specific, substantial and credible* asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The wide ranges provided for the many parameters of the light source coupled with the variables of the treatment site would require excessive experimentation for one skilled in the art to use the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12-19, 24, 29-37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,514,243 to Eckhouse et al. Eckhouse et al. teaches methods

for electromagnetic skin treatment using pulsed light sources such as flashlamps for providing electromagnetic treatment of the skin (abstract). The flashlamp is disclosed as providing energy with a wavelength between 550 and 1300 nm (Col. 6, lines 37-38), a pulse width of less than 200 ms, and the delay between pulses is on the order of 10 to 100 ms between the pulses (Col. 6, lines 39-41). The fluence is disclosed as between 10 and 100 J/cm^2 (Col. 6, line 22). The parameters of the incoherent light overlap those of the application and are therefore interpreted as an effective amount of electromagnetic radiation. The method of treatment with light energy comprises the steps of providing a high power, pulsed light output from a non-laser, incoherent light source and directing the pulsed light output to a treatment area (Col 4. line 64 to Col. 5 line 1). Since the application may be before, during or after exposure, there are no other options, so Eckhouse must be performed at one of those optional times. The presence or absence of visible damage does not affect the method of application. It is interpreted as a determinate as to whether treatment will or will not be performed only.

Regarding claims 2, 3 and 29, Eckhouse et al. teaches that during operation light is typically applied to the skin in a sequence of three pulses with short delays between the pulses (Col. 16, lines 51-53) indicating a predetermined number of pulses and more than one pulse.

Regarding claims 16 and 17, Eckhouse et al. teaches the wavelengths selected as being absorbed by melanin (Col. 21, lines 45-50).

Eckhouse does not disclose expressly the bursts of pulses, number of pulses, interval between pulses or time relation of the treatment (before, during or after). The applicant cites a plethora of possible treatment regiments and operational parameters with no criticality to any of the parameters. It is therefore implied that the primary goal is to provide a fluence level to the treatment area. Once a required fluence is known and any limitations to treatment, such as tissue temperature, the selection of treatment parameters and iterations would have been

obvious to a person of ordinary skill in the art, as the interrelations of the parameters are well known in the art.

Claims 1, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,676,655 to McDaniel. McDaniel teaches a method for treating various dermatological conditions using electromagnetic radiation with wavelengths from about 300 nm to about 1600 nm, and wherein said pulses have a duration of from about 0.1 femtoseconds to about 100 seconds, the interpulse delay between said pulses is from about 0.1 to about 1000 milliseconds, and the energy fluence received by said tissue is less than about 10 J/cm^2 (Col. 2, lines 28-34). These parameters overlap those of the application and are therefore interpreted as an effective amount of electromagnetic radiation. The method of treatment comprises the step exposing tissue to the light of the stated parameters (Col. 2, lines 25-27). Since the application may be before, during or after exposure, there are no other options, so McDaniel must be performed at one of those optional times. The presence or absence of visible damage does not affect the method of application. It is interpreted as a determinate as to whether treatment will or will not be performed only.

Regarding claims 25 and 26, McDaniel teaches the use of porphyrin as an excellent topical composition with superior optical properties for acting as a chromophore to enhance low-intensity light therapies (Col 22, line 33-37).

Regarding claim 27, McDaniel teaches that ultrasound may be used therapeutically to interact directly with the agent or the agent-tissue complex to produce the desired damaged target tissues (to be used alone or in combination with laser or non-laser light sources)(Col. 6, line 66 to Col. 7 line 3).

Regarding claim 28, McDaniel discloses low energy electromagnetic fields can be used alone or in combination with photomodulation (Col. 15, lines 55-60).

The applicant cites a plethora of possible treatment regiments and operational parameters with no criticality to any of the parameters. It is therefore implied that the primary goal is to provide a fluence level to the treatment area. Once a required fluence is known and any limitations to treatment, such as tissue temperature, the selection of treatment parameters and iterations would have been obvious to a person of ordinary skill in the art, as the interrelations of the parameters are well known in the art.

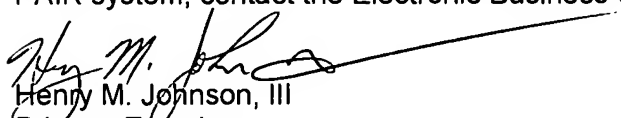
Claims 22, 23, 38, 39, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,514,243 to Eckhouse et al (Eckhouse) in view of U.S. Patent 6,730,113 to Eckhardt et al. (Eckhardt). Eckhouse is discussed above, but does not teach the use of a detecting film. Eckhardt discloses the use of a color-changing material, such as a photochromic or fluorescent ink or dye as a film on bandage to detect radiation level. The color-changing material may change color or emit light when exposed to UV light. Alternatively, the color-changing material may change color or emit light when exposed to light from another portion of the spectrum (Col 12, lines 50-60). Eckhouse et al. teaches sensors to detect varying skins or a difference between skin and bandage using reflectance. Such a sensor is capable of detecting reflectance of the marker dye or film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the color-changing film and sensors to detect radiation of Eckhardt in the invention of Eckhouse to monitor the radiation level to insure proper levels of radiation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Primary Examiner
Art Unit 3739